

MAY 13 2014

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92.(c)

Purpose of Submission: Vital Images, Inc. hereby submits this traditional 510(k) to provide notification submission of Vitrea Image Denoising software as an addition to the existing tools on the 510(k) cleared Vitrea platform.

Submitter: Vital Images, Inc.
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Establishment Registration: 2134213

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510(k) Type: Traditional

Summary Date: February 14, 2014

Device Name

Trade Name: Vitrea® Image Denoising Software
Common Name: Image Enhancement System
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050, LLZ)
Regulatory Description: Picture Archiving and Communications System

Predicate Device: Sapheneia Commercial Products AB, Sapheneia Clarity™ (K063391)

Device Description:

The Vitrea Image Denoising software is a tool available on the Vitrea platform. It assists radiologists and specialists in the enhancement and viewing of CT and 3D-XA images from a variety of diagnosis imaging systems by noise reduction and contrast enhancement. Vitrea Image Denoising software employs 3D analysis of the image structure of each voxel. Random noise does not have a 3D structure and can thus be separated from dominant structures. Once the structure has been determined, the denoising tool suppresses noise by averaging voxel information without removing important structural details for reducing the noise.

It provides a control to turn on or off a denoising preset in Multi-planar Reformatting (MPR) and 3D views to reduce noise and enhance contrast in reconstructed CT and 3D-XA image datasets, while preserving structural details of contrast, spatial size, and 3D structure in the native images for visual assessment. The user can interactively apply and remove the noise reduction filter during the image review to assess the effect of the noise reduction on the images and generate a new series of denoised snapshots for further review in other workstations or PACS. The denoised images can be used in conjunction with the original images as the user can switch between the original image and the denoised image while conducting image review. It also enables the user to create new denoising presets, edit existing denoising presets, and save the current denoising values as a custom preset.

Intended Use / Indications for Use:

Vitrear[®] Image Denoising software is intended to assist radiologists and specialists in the enhancement of CT and 3D-XA image presentation by enabling noise reduction and contrast enhancement technique.

Intended for Disease / Condition / Patient Population:

Not applicable as this is a medical image post processing software tool for image enhancement.

Substantial Equivalence:

With regards to safety, the Vitrea Image Denoising software is substantially equivalent to the currently marketed post-processing noise reduction software products that analyze data from medical images. Specifically, intended use, design, function and performance characteristics of Vitrea Image Denoising software are substantially equivalent to the Sapheneia Clarity (K063391) Image Enhancement System, which is manufactured by Sapheneia Commercial Products AB ("predicate device").

The comparison table below shows the equivalence between Vitrea Image Denoising software and the predicate device:

Vitrear Image Denoising (Submission Subject)	Sapheneia Clarity (K063391) (Predicate Device)	Noted Differences
Intended Use:		
Vitrear [®] Image Denoising software is intended to assist radiologists and specialists in the enhancement of CT and 3D-XA image presentation by enabling noise reduction and contrast enhancement technique.	<p>The Sapheneia Clarity is intended for use by radiologists for transfer, storage, noise reduction, contrast enhancement and viewing of multi-modality images from a variety of diagnostic systems.</p> <p>The device is also intended to be used by trained/qualified technologists for installation and maintenance of the software. For your legal protection, it is strongly recommended that you backup your original data.</p> <p>For digital mammography, only DICOM 'For Presentation' images should be displayed for primary image diagnosis.</p>	None
Intended Users:		
Radiologists and specialists.	Radiologists and technologists.	None

Vitrear Image Denoising (Submission Subject)	Sapheneia Clarity (K063391) (Predicate Device)	Noted Differences
Modality Support:		
CT and 3D-XA.	Multi-modality (CT, MR, 3D-XA).	Our software supports CT and 3D-XA datasets as the predicate device. Note: Our software does not support MR datasets.

The technological comparison table below shows the equivalence between Vitrea Image Denoising software and the predicate device:

Vitrear Image Denoising (Submission Subject)	Sapheneia Clarity (K063391) (Predicate Device)	Noted Differences
Device Description:		
Vitrear Image Denoising software is a software tool available on the Vitrea platform. It assists radiologists and specialists in the enhancement and viewing of CT and 3D-XA modality images from a variety of diagnosis imaging systems by noise reduction and contrast enhancement.	The Sapheneia Clarity image processing software reduces noise and enhances contrast of relevant structures to increase image quality through structure adaptation, tissue adaptation, scale adaptation, and noise adaptation.	None
Random noise does not have a 3D structure and can thus be separated from dominant structures.	Using robust estimation methods the dominant structures are separated from the embedding noise.	None
Once the structure has been determined, it is possible to suppress noise by averaging voxel information without removing important structural details for reducing the noise.	Once the structure has been determined, it is possible to strengthen the interesting parts while simultaneously reducing the noise.	None
The acquisition remains the same, i.e., the image processing can be generated from CT and 3D-XA modalities and with predefined or specific acquisition protocol settings.	The acquisition remains the same, i.e. the image processing can be generated from multiple modalities and with predefined or specific acquisition protocol settings.	None

Vitrear Image Denoising (Submission Subject)	Sapheneia Clarity (K063391) (Predicate Device)	Noted Differences
Characteristics:		
Image Enhancement System.	Image Enhancement System.	None
Where Used (Hospital, Home, Ambulance, etc.)		
Medical facility.	Medical facility.	None
User Interface:		
The software is designed for use on a radiology workstation.	The software is designed for use on a radiology workstation.	None
DICOM Standard Compliance:		
The software processes DICOM 3.0 compliant image data.	The software processes DICOM 3.0 compliant image data.	None
Noise Reduction Method:		
Image-space noise reduction method.	Image-space noise reduction method.	None
Separation of embedding noise from dominant structures.	Separation of embedding noise from dominant structures.	None
Level:		
Voxel (volumetric pixel) level noise reduction.	Pixel level noise reduction.	None

Vitrear Image Denoising (Submission Subject)	Sapheneia Clarity (K063391) (Predicate Device)	Noted Differences
Vitrear Image Denoising software employs 3D analysis of the image structure in the neighborhood of each voxel.	Sapheneia Clarity employs a sophisticated statistical analysis of the image structure in the neighborhood of each pixel.	Both methods aim at distinguishing structure from noise. Statistical analysis distinguishes between the two by studying the statistical distribution of the data whereas 3D analysis studies the first and second order derivatives of the image data to determine the dominant direction of structure if it exists.

Vital Images believes that Vitrear Image Denoising software has the same intended use i.e. enhancement of CT and 3D-XA images, similar indication statement i.e. to be used by trained radiologists and specialists at a medical facility, and similar technological characteristics i.e. image-space noise reduction method as the predicate device.

The above noted difference in the method of image structure analysis, i.e. Vitrear Image Denoising software uses 3D analysis and Sapheneia Clarity uses statistical analysis method to analyze image structure; does not alter the end result of the software, which is to distinguish structure from noise.

Vital Images believes that the verification and validation results demonstrate that Vitrear Image Denoising software is as safe and effective as the predicate device and raises no new issues of safety and effectiveness as compared to the predicate devices. Therefore, Vital Images believes that FDA should find Vitrear Image Denoising software to be substantially equivalent to the predicate device, Sapheneia Clarity.

Summary of Non-Clinical Tests:

The software was designed, developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new feature operates according to its requirements and without impact to existing functionality. Testing included verification, validation, and evaluation of previously acquired medical images.

The following quality assurance measures were applied to the development of Vitrear Image Denoising software:

- Risk analysis
- Requirements reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included phantom testing and simulated usability testing by independent experienced medical professionals.

Risk analysis:

Vital Images performed a risk analysis, referring to software hazards associated with the intended use, including severity assessment and mitigation. The analysis was based upon the application of ISO 14971:2012 risk management to medical devices, in compliance with medical device ISO 13485:2012 and IEC 62304:2006 requirements.

All identified risks were reduced as low as possible. The medical benefits of the software outweigh the residual risk for each individual risk and all risks together. The overall residual risk for the software was deemed acceptable.

Verification:

The software verification team's primary goal is assuring the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:

The software validation team's primary goal is assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

Internal Validation (Phantom Testing):

The software validation team provided internal validation of Vitrea Image Denoising software. Internal validation included internal beta testing and internal user acceptance testing using various Catphan phantoms. The performed phantom tests validated that the amount of noise reduction is clinically significant considering the clinical use of the filter and the resulting spatial resolution, the level of image sharpness or spatial resolution after noise reduction remains acceptable for the diagnostic purposes and the low contrast resolution is not degraded after the noise reduction.

External Validation:

During external validation of Vitrea Image Denoising software, experienced Radiologists and an Interventional Cardiologist evaluated the Vitrea Image Denoising software. Each user felt that the Vitrea Image Denoising software reduces noise and enhances contrast in reconstructed CT and 3D-XA image datasets, while preserving structural details of contrast, spatial size, and 3D structure in the native images for clinically relevant visual assessment.

Summary of Clinical Tests:

The subject of this traditional 510(k) notification, Vitrea Image Denoising software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***

The Vitrea platform relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.

- ***Integrity***

The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. Vitrea platform identifies the data it produces, marking and encoding the appropriate DICOM fields.

- ***Availability***

The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

- **Accountability**

The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standard:

The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

Vitrea Image Denoising software complies with following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Conclusion:

The testing reported in this 510(k) establishes that Vitrea Image Denoising software is substantially equivalent to the Sapheneia Clarity (K063391) Image Enhancement System and is as safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Vital Images, Inc.
% Mr. Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

Re: K140395
Trade/Device Name: Vitrea[®] Image Denoising Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2014
Received: February 18, 2014

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

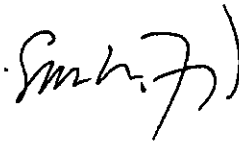
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K140395

Device Name: Vitrear® Image Denoising Software

Indications for Use:

Vitrear® Image Denoising software is intended to assist radiologists and specialists in the enhancement of CT and 3D-XA image presentation by enabling noise reduction and contrast enhancement technique.

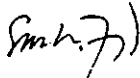
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K140395